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## NOTICE OF ALLOWANCE AND FEE(S) DUE

2101

7590

06/18/2009

BROMBERG & SUNSTEIN LLP  
125 SUMMER STREET  
BOSTON, MA 02110-1618

EXAMINER

OLSON, ERIC

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 06/18/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,111	07/13/2006	Dale Howard Hreczuk-Hirst	2667110	6287

TITLE OF INVENTION: POLYSIALIC ACID DERIVATIVES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	09/18/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN **THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE** OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

## HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER:** Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

# **PART B - FEE(S) TRANSMITTAL**

**Complete and send this form, together with applicable fee(s), to:** Mail **Mail Stop ISSUE FEE**  
**Commissioner for Patents**  
**P.O. Box 1450**  
**Alexandria, Virginia 22313-1450**  
**or Fax** **(571)-273-2885**

**INSTRUCTIONS:** This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

2101 7590 06/18/2009  
**BROMBERG & SUNSTEIN LLP**  
**125 SUMMER STREET**  
**BOSTON, MA 02110-1618**

## **Certificate of Mailing or Transmission**

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,111	07/13/2006	Dale Howard Hreczuk-Hirst	2667110	6287

TITLE OF INVENTION: POLYSIALIC ACID DERIVATIVES

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nonprovisional	NO	\$1510	\$300	\$0	\$1810	09/18/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
OLSON, ERIC	1623	514-049000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.  
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a **Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1  
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2  
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee  
☐ Publication Fee (No small entity discount permitted)  
☐ Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.  
☐ Payment by credit card. Form PTO-2038 is attached.  
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature \_\_\_\_\_ Date \_\_\_\_\_  
Typed or printed name \_\_\_\_\_ Registration No. \_\_\_\_\_

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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2101	7590	06/18/2009	EXAMINER	
BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618			OLSON, ERIC	
			ART UNIT	PAPER NUMBER

1623

DATE MAILED: 06/18/2009

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 229 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 229 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

**Notice of Allowability****Application No.**

10/568,111

**Examiner**

ERIC S. OLSON

**Applicant(s)**

HRECZUK-HIRST ET AL.

**Art Unit**

1623

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's communication submitted March 16, 2009.
2. ☒ The allowed claim(s) is/are 1,4-10,21-24,30 and 31.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

/Eric S Olson/  
Examiner, Art Unit 1623

/Shaojia Anna Jiang/  
Supervisory Patent Examiner, Art Unit 1623

### **Detailed Action**

This office action is a response to applicant's communication submitted March 16, 2009 wherein claims 1, 4-7, 9, 21, and 22 are amended, claims 2, 3, 11-19, and 25-29 are cancelled, and new claims 30 and 31 are introduced. This application is a national stage application of PCT/GB04/03488, filed August 12, 2004, which claims priority to foreign applications EP03254988.3, filed August 12, 2003, and EP03255300, filed August 12, 2003.

Claims 1, 4-10, 21-24, 30, and 31 are pending in this application.

Claims 1, 4-10, 21-24, 30, and 31 as amended are examined on the merits herein.

### **Reasons for Allowance**

Applicant's amendment to the specification, submitted March 16, 2009, has been fully considered and is not seen to introduce any new matter into the disclosure, as the previous paragraph (p. 7 lines 22-26) clearly indicate that the sialic acid and the cysteine are linked through a thioether group, and furthermore a linkage between N-succinimide and cysteine at the alpha position is typically a thioether linkage. Therefore the objection to the specification of record in the previous office action is withdrawn.

Applicant's amendment, submitted March 16, 2009, with respect to the rejection of instant claim 9 under 35 USC 112, first paragraph, for lacking written description for conjugates linked by a thioester bond, has been fully considered and found to be

persuasive to remove the rejection as claim 9 has been amended to refer to a thioether rather than a thioester. Therefore the rejection is withdrawn.

Applicant's amendment, submitted March 16, 2009, with respect to the rejection of instant claims 1-8, 10, 23, and 24 under 35 USC 103(a) for being obvious over Gregoriadis et al. in view of Ashkenazi et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the polysaccharide be attached by its reducing end. Therefore the rejection is withdrawn.

The requirement for restriction between claims 1, 4-10, 23, 24, 30, and 31 and claims 21 and 22 is withdrawn in view of the allowability of claims 1 and 5 from which claims 21 and 22 depend. Therefore claims 21 and 22 are rejoined. All claims have been examined on the merits herein.

Currently claims 1, 4-10, 21-24, 30, and 31 are pending in this application and have been examined on the merits herein. Applicant's amendment submitted March 16, 2009, is seen to be persuasive to remove all rejections of record in the previous office action and place the application in condition for allowance. Reasons for allowance are as follows:

The claimed subject matter is seen to be adequately described and enabled by the specification as originally filed. P. 3 lines 19-31 of the specification describes the general concept of a sialic acid linked to a protein, by either the reducing or nonreducing

end. P. 4 lines 5-14 specifically discloses attaching the protein to the terminal reducing unit. Different linkages including maleimido, iodoacetamide, vinylsulfone, and orthopyridyl disulfide are disclosed on p. 5 lines 4-13. The structure of claim 7 is already disclosed in the claims as originally filed. Polysialic acids are disclosed as a preferred embodiment of the polysaccharide on pp. 6-7 of the specification. Pp. 9-18 disclose methods for making these compounds that would obtain one skilled in the art to synthesize the claimed conjugates. Therefore the claimed invention meets the requirements of 35 USC 112.

Furthermore the claimed invention is seen to be novel and non-obvious over the specification as originally filed. The prior art does not disclose polysialic acid conjugates or any other polysaccharide conjugates having two sialic acid units according to the claims wherein the pendant moiety is linked at the reducing end, as opposed to the non-reducing end. Although some prior art references, such as Gregoriadis et al., discloses sialic acid polysaccharides having attached pendant groups, these conjugates are modified at the non-reducing end by oxidation of the vicinal diol group. There is no teaching in the prior art to use the reducing end, and in fact the non-reducing end is used because of the easy availability of the vicinal diol group on the non-reducing end of polysialic acid. As disclosed on p. 4 lines 5-8 of the specification, when attaching a conjugate at the reducing end of a polysialic acid containing polysaccharide it is preferred to carry out a preliminary deactivation step on the polysaccharide to inactivate the non-reducing end before derivatizing the reducing end. This is because of the reactive diol group on the non-reducing end which would

easily react with the oxidation and derivatization reagents used to derivatize the reducing end. One of ordinary skill in the art would not have introduced extra complexity into the reaction without any expectation that the result would be superior to simply derivatizing at the reducing end. Therefore the claims meet the requirements of 35 USC 102 and 103.

Accordingly, Applicant's amendment submitted March 16, 2009, is sufficient to remove all rejections made in the prior office action as discussed above and to place the application in condition for allowance.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled, "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/  
Examiner, Art Unit 1623  
6/13/2009

/Shaojia Anna Jiang/  
Supervisory Patent Examiner, Art Unit 1623